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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,760	12/21/2000	Richard Glynn	18547-046600US	4702

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/19/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/747,760

Applicant(s)
Mack et al

Examiner
Padmashri Ponnaluri

Art Unit
1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 4, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) 3-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 14 6) ☐ Other:

Art Unit: 1639

DETAILED ACTION

1. The amendment and response filed on 3/4/03 has been fully considered and entered into the application.
2. Claims 1-21 are currently pending in this application.
3. This application contains claims 3-21 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CAR 1.144) See MPEP § 821.01.
4. Claims 1-2 are currently being examined in this application.
5. The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Foulkes et al (US Patent 5,580,722) set forth in the previous office action has been withdrawn in view of the amendment.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/10365 (LOCKHART et al) and Grosveld et al (US Patent 6,110,666) for the reasons set forth in the previous office action mailed on 11/4/02.

New Rejections Necessitated by the Amendment

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1639

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foulkes et al (US Patent 5,580,722) and Cruse et al (Illustrated Dictionary of Immunology, 1995, pages 56 and 59, CRC Press New York).

The instant claims briefly recite a method of screening drug candidates by adding a drug candidate to B cell that expresses expression profile of one or more genes, and determining the effect of the drug candidate on the expression of the expression profile of the one or more genes.

Foulkes et al disclose a method to determine whether a molecule not previously known to be a modulator pf protein biosynthesis is capable of directly and specifically transcriptionally modulating the expression of a gene encoding a protein of interest associated with treatment of one or more symptoms of a cardiovascular disease (i.e., see abstract). The reference discloses that the cardiovascular disease may be associated with thrombosis (i.e., see column 21). The reference

Art Unit: 1639

discloses that the protein of interest may be CD36 (i.e., see column 21, line 66) (refers to one of expression profile gene of the instant claims). The reference discloses in claim 1, a method of determining whether a chemical not previously known to be modulator of protein biosynthesis (refers to drug candidate of the instant claims) is capable of modulating expression of a gene encoding a protein of interest, by contacting the sample which contains the predefined eukaryotic cells consisting of gene encoding protein of interest (refers to the cell of the instant claims); quantitatively determining the amount of the signal so produced (refers to step c) of the instant claims); comparing the amount so determined with the amount of produced signal detected in the absence of any chemical being tested refers to instant claim 2).

The claimed invention differs from the prior art by reciting that the cells used in the claimed method are 'B cells'. Foulkes et al do not teach that the cells used in the claimed method are B cells. However, the reference teaches the gene encoding the protein of interest is CD36 (refers to the one of the expression profile gene of the instant claims). And it is well known in the art that CD36 is also found on the B cells. The Dictionary of immunology by Cruse et al disclose that CD36 is found weakly on B cells. Thus, the cells used by the reference can be B cells, since the cells used in the reference method express CD36. Thus, it would have been obvious to one skilled in the art at the time the invention was made to use different types of cells to monitor the gene expression profile in presence of a drug.

10. Applicant's arguments filed on 3/4/03, regarding the rejection of claims over LOCKHART et al and Grosveld et al have been fully considered but they are not persuasive.

Art Unit: 1639

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/10365 (LOCKHART et al) and Grosveld et al (US Patent 6,110,666) .

LOCKHART et al teach methods of monitoring the expression levels of a multiplicity genes. The reference teaches a method of identifying genes that are effected by one or more dugs, or conversely screening a number of drugs to identify those that have effect on particular genes (i.e., see page 8, lines 31-32 and the line bridging pages 8 and 9). The method provides a pool of target nucleic acids from one or more cells (refers to the instant clams steps a) and b)) contacted with the drug or drugs and hybridizing that pool to any of the high density oligonucleotide arrays. The reference teaches that the expression levels of the genes targeted by the probes in the array are determined and compared to expression levels of genes from control cells not exposed to the drug or drugs (refers to instant claim 2) (i.e., see page 9, lines 1-6). The genes that are over expressed or under expressed in response to the drugs are identified or conversely the drug or drugs that alter expression of one or more genes is identified (i.e., see page 9, lines 6-8).

The reference teaches that the genes of particular interest for expression monitoring include genes involved in pathways associated with various pathological conditions (e.g., cancer) and whose expression is thus indicative of the pathological condition. Such genes include but are not limited to HER2 (c-erbB-2/neu), receptor protein kinases associated with etiologi of number of tumors including carcinomas of breast, liver, bladder, pancreas as well as glioblastomas, sarcomas, squamous carcinomas, tumor suppressor genes such as p53 and other marker genes such as RAS, MSH2, MLH1, BRCA1. Other genes of particular interest for expression monitoring are genes involved in the immune responses, as well genes involved in cell adhesion and signal transduction, etc. (I.E., see page 8, lines 19-29).

The claimed invention differs from the prior art teachings by reciting specific cells that express specific genes (CD72 is the elected gene). LOCKHART et al teaches a method of identifying genes that are effected by one or more dugs. The reference teaches that the genes of particular interest for expression monitoring include genes involved in pathways associated with various pathological conditions, and genes involved in immune responses, cell adhesion and signal transduction. The reference does not teach cells that express CD72. However, Grosveld et al (US Patent 6,110,666) teaches pre-B cell possess CD72 as cellular marker gene (i.e., see column 8, lines 8-9). The reference

Art Unit: 1639

teaches a composition for targeted gene delivery to a target cell composing immune cell surface antigen CD72 (i.e., see column 22, lines 65-66). The reference teaches monitoring the levels of transduction, gene expression and/or the presence or levels of normal encoded protein will assist in selecting and adjusting the dosage administered (i.e., see column 23, lines 34-36).

Thus it would have been obvious to one skilled in the art at the time the invention was made to use the cells that express CD72 gene taught by Grosveld et al in the drug screening methods, because LOCKHART et al teach a method of identifying genes that are effected by one or more dugs, LOCKHART et al teaches that the genes of particular interest for expression monitoring include genes involved in pathways associated with various pathological conditions, gene s involved in immune response.

Applicants argue that the present claims are not directed to screening methods that determine the effect of drugs on 'pre-B cells', Instead the methods are conducted with "B cells" which are further along the lymphocyte differentiation pathway.

Applicants arguments have been considered but are not persuasive, since LOCKHART et al teach the method of screening drugs by monitoring the expression of certain genes. Grosveld et al teach expression of CD72 as a marker for pre-B cells. Applicants have amended the claims to read as "B cells" in the claimed method. Grosveld et al teach CD72 as a marker for Pre-B cells. And CD72 is well known in the art as a marker for B cell (i.e., in the Illustrated Dictionary of Immunology states that CD72 is Pre-B cell marker, and the antigen is expressed from Pro-B cell stage until the plasma cell stage). Thus, the instant claimed method is obvious to one skilled in the art from the teachings of Grosveld et al and LOCKHART et al of record.

Art Unit: 1639

11. No claims are allowed.
12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Art Unit: 1639

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Primary Examiner
Technology Center 1600
Art Unit 1639
15 May 2003


PADMASHIRI PONNALURI
PRIMARY EXAMINER